

AMENDMENTS TO THE SPECIFICATION

Please amend paragraph [0151] as follows:

[0151] It may be noted that the disadvantageous outward forces (e.g., forces 40 as described with reference to Fig. 2A, and forces 54 such as described with reference to Fig. 3B) refer to forces that cause motion of the foreign body capsule relative to the device as a whole. In other words, the discontinuity of the surface on which the sensing region is located creates outward forces of the FBC as a whole, which unfortunately allows motion of the device within the FBC. These outside forces 40 create a thickened FBC due to chronic inflammatory response responsive to motion of the device within the FBC such as described with reference to Figs. 2 and 3. It may be noted however that a biointerface material with interconnected cavities in at least a portion thereof may be placed over the sensor head such as described with reference to copending U.S. Patent Application / , 10/647,065, filed on even date herewith and entitled “POROUS MEMBRANE FOR USE WITH IMPLANTABLE DEVICES”, which is incorporated herein in its entirety by reference. This biointerface material advantageously causes disruption of the contractile forces caused by the fibrous tissue of the FBC within the cavities of the biointerface material. Particularly, the biointerface material includes interconnected cavities with a multiple-cavity depth, which may affect the tissue contracture that typically occurs around a foreign body. That is, within the cavities of the biointerface material, forces from the foreign body response contract around the solid portions that define the cavities and away from the device. This architecture of the interconnected cavities of the biointerface material is advantageous because the contractile forces caused by the downward tissue contracture that may otherwise cause cells to flatten against the device and occlude the transport of analytes, is instead translated to and/or counteracted by the forces that contract around the solid portions (e.g., throughout the interconnected cavities) away from the device. Therefore, the mechanisms of the present invention (e.g., geometric configurations described herein) are designed to increase downward forces on the sensor head in order to decrease motion of the device relative to the FBC as a whole, which complements the mechanisms of the biointerface material that causes disruption of the contractile forces within the biointerface material in order to deflect the forces toward the solid portions within the biointerface and away from the device itself, both of which

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mechanisms work to prevent the formation of occlusive cells that block analyte transport. Therefore, a biointerface material such as described above may be placed over at least a portion (e.g., some or all) of the sensing region of the devices of the present invention to aid in preventing the formation of occlusive cells (e.g., barrier cell layer) and increasing the transport of analytes.

Please amend paragraph [0156] as follows:

[0156] Perpendicular forces 88, depicted in Fig. 5C by arrows pointing down, reduce or eliminate shear forces with the tissue at the sensor head. While lateral forces 90 may appear to create shear forces at the sensor head, several features of the sensor mitigate these forces. For example, the sensor is much thinner and is immediately adjacent to the fascia, underlying the fat, making it less prone to movement. As another example, the sensor may be sutured to the tough fascia, which further prevents lateral forces from being conveyed to the sensor head; while in other preferred embodiments, an anchoring material or other method of attachment may be employed. As yet another example, in order to facilitate proper healing, the side of the sensor upon which the sensor head is situated preferably has a curved radius extending from lateral side to lateral side. As depicted in the side view and end view (Figs. 5C and 5D), the sensor head is positioned at the apex of the radius. When surrounding tissue contracts as it heals, the radius serves to optimize the forces 88 exerted down onto the curved surface, especially the forces in the lateral directions 90, to keep the tissue uniformly in contact with the surface and to produce a thinner foreign body capsule. The curvature ensures that the head is resting against the tissue and that when tissue contraction occurs, forces are generated downward on the head so that the tissue attachment is maintained. It may be noted that the downward forces bring the tissue into contact with porous biointerface materials used for ingrowth-mediated attachment and for biointerface optimization, such as described above and in copending U.S. Patent Application 10/647,065, filed on even date herewith and entitled "POROUS MEMBRANE FOR USE WITH IMPLANTABLE DEVICES". While it is preferable to have a curved radius extending longitudinally, in certain embodiments it may be acceptable to incorporate a longitudinally flat surface or longitudinal surface with another configuration. In a device as depicted in Fig. 5C, the radius of curvature in the lateral direction is preferably about 2.7 cm.

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Please amend paragraph [0164] as follows:

[0164] As a first noted advantage, the cylindrical geometry of the sensor body 120 allows for discreet placement within or between tissue types when the overall surface area-to-volume ratio can be optimized to provide a maximal surface area with a minimal volume. That is, although the volume of a sensor often depends on the necessary electronics within the sensor body, the evolution of smaller batteries and circuit boards sanctions the design and manufacture of a cylindrical sensor with minimal volume; simultaneously, the surface area inherent in a cylindrical geometry allows for maximal tissue anchoring *in vivo* (e.g., as compared to a substantially rectangular or oval structure). In one exemplary embodiment, an application specific integrated circuit (ASIC) may be designed to fit within the geometric design of any of the embodiments disclosed herein to maximize the electronic capabilities while minimizing volume requirements as compared to conventional circuit boards. Sensor electronics requirements vary depend on the sensor type, however one example of electronics for a glucose sensor is described in more detail with reference to copending U.S. Patent Application ____, 10/633,367, filed on August 1, 2003 and entitled “SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA,” which is incorporated by reference herein in its entirety.

Please amend paragraph [0189] as follows:

[0189] In a preferred embodiment, the sensor is formed by substantially entirely epoxy encapsulating the sensor electronics; that is, the sensor body, outside the sensor head, is comprises an epoxy resin body. During the manufacture of the sensor body of the preferred embodiment, the sensitive electronic parts (e.g. battery, antenna, and circuit board, such as described in copending U.S. Patent Application ____, 10/633,367, filed on August 1, 2003 and entitled “SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA”) are substantially entirely encapsulated in epoxy, with the exception of the sensor head. In some molding processes, the epoxy body may be formed with a curvature on a portion thereof. After the epoxy has completely cured, additional curvature may be machined, milled, laser-etched, or

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otherwise processed into the epoxy body to form the final geometric shape. In alternative embodiments, a light epoxy coating may be applied to the sensitive electronic parts, after which injection molding or reaction injection molding (RIM) may be used to form the final shape of the epoxy body. While a preferred sensor is constructed of epoxy resin, a non-conductive metal, ceramic or other suitable material may be used.

Please amend paragraph [0208] as follows:

[0208] Fig. 14A is a graph showing the percentage of functional sensors from the two different sensor geometry groups. The x-axis represents time in weeks; the y-axis represents percentage of functional sensors for each group during the weekly infusion studies. It is known that an initial startup period exists for sensors implanted in the subcutaneous space, between about one and three weeks, during which delayed sensor functionality may be related to the amount and speed of tissue ingrowth into the biointerface, as described with reference to copending U.S. Patent Application / , 10/647,065, filed on even date herewith and entitled “POROUS MEMBRANE FOR USE WITH IMPLANTABLE DEVICES.” Interestingly, both sensor geometries functioned substantially as expected in that the majority of devices were functional by week four. However, the sensors of the thin, oblong sensor geometry group showed faster start-up times as evidenced by a higher percentage of functional sensors at weeks two and three.

Please amend paragraph [0211] as follows:

[0211] Fig. 14B is a graph showing the average R-value of sensors from a study of the two different sensor geometries implanted in a host. The x-axis represents time in weeks; the y-axis represents average R-value for each group of sensors during each weekly infusion study. R-values were obtained by correlating sensor output to the externally derived meter values, and performing a least squares analysis, such as described with reference to copending U.S. Patent Application / , 10/633,367, filed on August 1, 2003 and entitled “SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA.”